Limitations of the Outback LTD re-entry device in femoropopliteal chronic total occlusions

Susanna H. Shin, MD, Donald Baril, MD, Rabih Chaer, MD, Robert Rhee, MD, Michel Makaroun, MD, and **Luke Marone, MD,** *Pittsburgh, Pa*

Objective: **Subintimal recanalization for the treatment of femoropopliteal chronic total occlusions (CTO) occasionally requires re-entry devices to access the true lumen distally, but limited information is available on factors predicting the success or failure of these devices. We evaluated the Outback LTD re-entry device (LuMend, Redwood City, Calif; acquired by Cordis Corp, Miami Lakes, Fla).**

Methods: **A retrospective review of patients with femoropopliteal CTO from August 2006 to August 2009 was performed. Age, gender, occlusion length, site of re-entry, and the angle of the aortic bifurcation were recorded. Procedural angiograms were used to assign a calcification score (none, mild, moderate, severe) at the re-entry site. Univariate and multivariate logistic regression analyses were used to identify factors predicting failure of re-entry into the true lumen.**

Results: **Of 249 CTOs treated, the re-entry device was used 52 times (20.9%): 47 superficial femoral artery (SFA) occlusions and 5 combined SFA and popliteal artery occlusions (33 TransAtlantic InterSociety Consensus II type C and 18 type D lesions). Of 48 procedures with available angiograms for review, the target re-entry site was at the adductor canal in 30 (62.5%), the above-knee popliteal artery in 13 (27.1%), behind the knee joint in 4 (8.3%), and the mid-SFA in 2 (4.2%). Patients (54% men) were a mean age of 73.1 years. Re-entry was successful in 34 attempts (64.5%). Causes of failure included inability to re-enter the true lumen in 11 (61.1%), difficulty tracking the device over a wire in 3 (16.7%), acute angle of aortic bifurcation in 2 (11.1%), mechanical failure of the device in 1 (5.6%), and difficulty tracking the device through the lesion in 1 (5.6%). Moderate or severe calcification at the site of re-entry was the only significant predictor of failure (odds ratio, 6.3; 95% confidence interval, 1.45-24.48; $P = .01$). An aortic bifurcation angle ≥40° did trend toward predicting success (odds ratio, 0.23; 95% confidence interval, 0.05-1.02; $P = .054$).**

Conclusions: **Although the Outback re-entry device can be successful in extending the applicability of endovascular management to difficult femoropopliteal occlusions, it is not uniformly successful in current clinical practice. Significant calcification at the proposed re-entry site is a strong predictor of failure. (J Vasc Surg 2011;53:1260-4.)**

Subintimal angioplasty with recanalization of chronic total occlusions (CTOs) is the accepted first-line therapy for TransAtlantic InterSociety Consensus (TASC) II B and C lesions in the femoropopliteal location. Subintimal angioplasty, first described by Bolia et al,[1] is performed by creating entry into the subintimal plane using hydrophilic wires and crossing catheters and then establishing re-entry into the true lumen with similar wire and catheter techniques. The primary limitation of this technique is true lumen re-entry distal to the occluded segment, with reported failure rates of 16.5% to 26%.

In addition, conventional re-entry techniques may be possible but only distal to the vessel reconstitution point, leading to the sacrifice of significant collateral vessels.[2,3] These difficulties with re-entry have prompted the introduction of re-entry devices such as the Pioneer catheter (Medtronic Inc, Minneapolis, Minn) and the Outback LTD catheter (LuMend, Redwood City, Calif [acquired by Cordis Corp, Miami Lakes, Fla]).

The Pioneer catheter uses intravascular ultrasound to guide a retractable curved nitinol needle into the true lumen. The Outback catheter uses 2-dimensional fluoroscopy to guide a retractable curved nitinol needle into the true lumen. Previous studies have shown variable success of 50% to 100% with these re-entry devices in the treatment of infrainguinal CTOs.[2-7] Previous reports indicate the primary limitation of these devices is heavy calcification at the proposed site of true lumen re-entry; however, these were small series that included various vascular beds.[2,6,7] In this study, we examined the success and the predictors of failure of using the Outback LTD device in CTOs of the femoropopliteal segment that have failed conventional re-entry techniques.

METHODS

Institutional Review Board approval was obtained for human research for this study from the University of Pittsburgh Medical Center. All procedures described in this series were performed by or under the supervision of attending vascular surgeons at the University of Pittsburgh Medical Center.

Patient selection. A retrospective review of a prospectively maintained database identified 249 patients with femoropopliteal CTOs treated endoluminally with subinti-

From the Division of Vascular Surgery, University of Pittsburgh Medical Center.

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Reprint requests: Susanna Shin, MD, UPP Vascular Surgery, UPMC Presbyterian, 200 Lothrop St, A-1017, Pittsburgh, Pa 15213 (e-mail: shins@upmc.edu).

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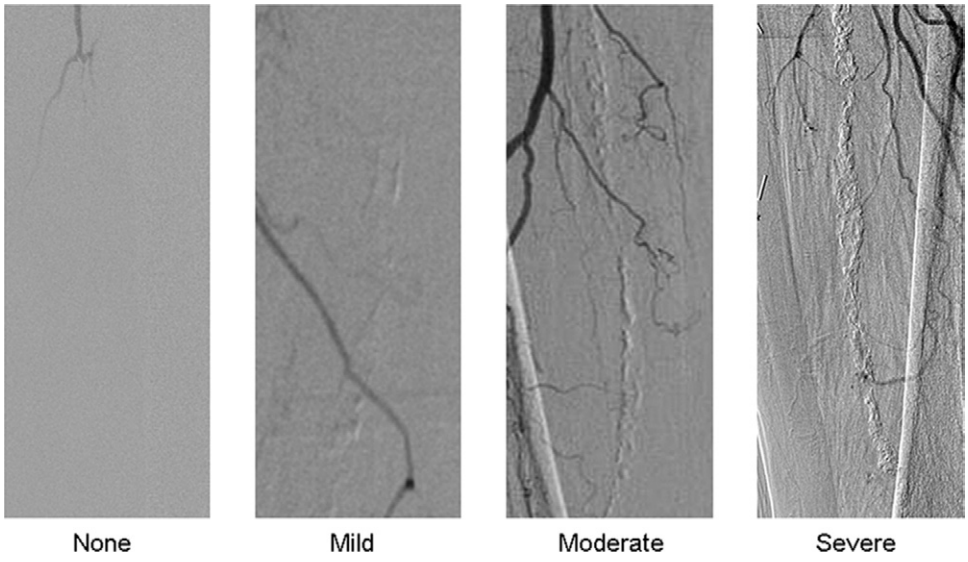

Fig 1. Calcification scoring system.

mal angioplasty, with and selective stenting, by our group from August 1, 2006, to August 31, 2009. Some patients in whom subintimal recanalization was attempted but unsuccessful were not included in this database and were lost to analysis in this study. This cohort included patients with prohibitive surgical risk undergoing intervention for critical limb ischemia (CLI) as well as patients being offered endovascular therapy as a primary modality in the treatment of CLI or intermittent claudication. From this series, we identified 52 procedures in which the Outback LTD re-entry catheter was used. Data collected included basic demographic data (age, gender) and details about the lesion, including location, length of occlusion, distal reconstitution site, and the 2007 TASC II classification.

Technique. All interventions were performed using fixed imaging in a dedicated angiography suite or hybrid operating room under conscious sedation with local 1% lidocaine anesthesia. Our preferred method of subintimal recanalization was through percutaneous access from a contralateral retrograde common femoral artery puncture. Deviation from this approach occurred when the anatomy was not amenable, and in such cases, an antegrade ipsilateral approach was used or puncture of a femoral-femoral bypass graft was performed.

All interventions were performed with systemic heparinization and the support of a 6F or 7F sheath ("up and over" technique with contralateral approach). Initial subintimal recanalization was performed with a 0.035-inch hydrophilic wire and a 4F or 5F hydrophilic catheter. If entry into the subintimal space was achieved using this technique but re-entry into the true lumen was not possible using multiple conventional re-entry maneuvers, then the attending vascular surgeon considered using the Outback LTD re-entry catheter (Fig 1).

The crossing catheter was left in the subintimal space and the 0.035-inch hydrophilic wire was exchanged for a 0.014-inch Spartacore guidewire (Guidant, Temecula, Calif). The Outback catheter was then placed over the Spartacore wire. Using fluoroscopy and road map imaging, the Outback catheter was oriented with the needle positioned toward the lumen distal to the occlusion. This involves imaging at two separate angles. Initially, the catheter was located parallel to the vessel with the radiopaque marker oriented as an "L" toward the lumen. The image intensifier was then rotated 90° orthogonally and the radiopaque marker was simultaneously oriented as a "T" over the center of the flow lumen. The needle was then deployed and the guidewire advanced through the needle.

The Outback catheter was removed and angioplasty was performed, with self-expanding stents placed when residual stenosis was >30% or flow-limiting dissection was identified. All re-entry attempts made with the Outback LTD catheter were performed at the most proximal vessel reconstitution point in an attempt to preserve chronic collateral perfusion.

Procedural details (wires, catheters and sheaths used, success of device, site of re-entry, reason for failure) were recorded from the procedure dictation. Anatomic details were assessed based on review of the procedural angiogram. The aortic bifurcation angle (ABA) was measured from the aortogram (abdominal and pelvic) using a built-in tool on the imaging software at our institution that allows the accurate measure of angles. The ABA was measured in the anterior-posterior view of the aortogram. An aortic bifurcation angle <40° was considered acute. Calcification at the region of the site of re-entry was considered because it might represent an obstacle to re-entry. Calcification at other sites of the artery was not considered in the analysis.

The degree of calcification at the site of re-entry was estimated by a single observer using angiographic images based on the presence of calcification on no side, one side, both sides of the artery, or circumferentially (Table I and

Table I. Calcification scoring system

Score	*Angiographic findings*
None	No calcification visible
Mild	Calcification visible only on one side of the vessel
Moderate	Calcification visible on both (lumen) sides of the vessel with lucent center
Severe	Calcification visible on both center (lumen) sides of the vessel without lucent

Fig 2). The aortic bifurcation angle and calcification for each patient was measured or estimated before categorization as success or failure of the Outback device.

Statistics. Statistical analysis was performed by an independent statistician using SAS 9.2 software (SAS Institute Inc, Cary, NC). Continuous variables were compared using the *t* test, and categoric variables were compared using the χ^2 or Fisher exact test. Logistic regression was used to model the association of variables with treatment failure. Odds ratios (ORs) are presented with 95% confidence intervals (CIs). Statistical significance was defined with a value of $P < .05$.

RESULTS

Infrainguinal recanalizations. From August 1, 2006, to August 31, 2009, 249 infrainguinal CTOs were treated with endoluminal techniques. Of these, 249 femoropopliteal lesions, 37.8% were TASC II C lesions and the rest were D lesions. Patients (52.4% men) were a mean age of 72.2 years.

Outback catheter. The Outback re-entry catheter was used in 52 limbs in 50 patients after traditional wire and catheter techniques failed to allow re-entry into the true lumen. A total of 47 superficial femoral artery (SFA) occlusions and 5 combined SFA and popliteal artery occlusions were treated (33 were TASC II C and 18 were TASC II D lesions). The mean patient age was 73.1 years, and 54.0% were men. The mean lesion length was 17.6 cm. True lumen re-entry with the Outback catheter was successful in 34 limbs (64.5%; Table II). The site of re-entry (attempted or successful) was most commonly the adductor canal (61.7%). Other sites included the above-knee popliteal artery (25.5%), directly behind the knee joint (8.5%), and the mid-SFA (4.3%). The mean ABA was 42.8° (range, 14°-95°). Overall, 29 ABAs (63.0%) were not acute. An ABA ≥40° trended toward being significant as a negative predictor of failure (protective factor) of the device (OR, 0.23; 95% CI, 0.05-1.02; $P = .054$).

Outback catheter failures. Moderate or severe calcification at the site of re-entry was the only significant predictor of failure (OR, 6.3; 95% CI, 1.45-24.48; $P = .01$). The most common reason for failure was inability to re-enter the true lumen, accounting for 11 failures (61.1%). In this subgroup as well, moderate or severe calcification at the attempted site of re-entry was a significant predictor of failure (OR, 7.5; 95% CI, 1.21-46.50; $P = .03$). Additional reasons for failure included 3 cases (16.7%) of difficulty

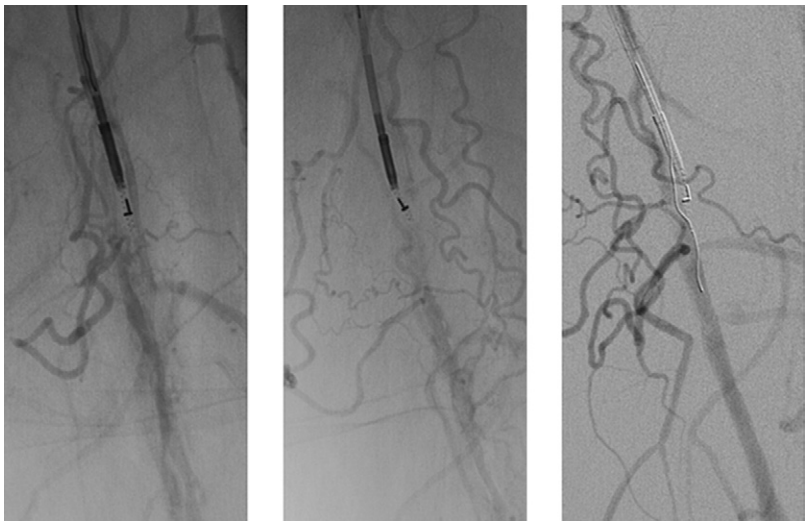

Fig 2. When Outback LTD re-entry catheter was considered for use, the crossing catheter was left in the subintimal space and the 0.035-inch hydrophilic wire was exchanged for a 0.014-inch Spartacore guidewire (Guidant, Temecula, Calif) and placed over the Spartacore wire. Using fluoroscopy and road map imaging, the Outback catheter is oriented with the needle positioned toward the lumen distal to the occlusion. This involves imaging at 2 separate angles. Initially, the catheter is located parallel to the vessel with the radiopaque marker oriented as an "L" toward the lumen. The image intensifier is then rotated 90 degrees orthogonally and the radiopaque marker is simultaneously oriented as a "T" over the center of the flow lumen. The needle is then deployed and the guidewire advanced through the needle. The Outback catheter is then removed and angioplasty performed with self-expanding stents placed when residual stenosis was > 30% or flow-limiting dissection was identified.

Table II. Characteristics of patients and lesions treated with Outback LTD re-entry catheter

Variable	*Successful (n = 34)*	*Failure (n = 18)*	P
Age, mean y	75.0	70.8	.23
Male, No. (%)	16 (47.1)	11 (61.1)	.39
TASC II C, No. (%)	21 (63.6)	11 (61.1)	>.99
TASC II D, No. (%)	12 (36.3)	7 (38.9)	
Lesion length, mean mm	184.5	181.8	.94
Calcification, No. (%)			
None/mild	29 (85.3)	10 (55.6)	.04
Moderate/severe	5 (14.7)	8 (44.4)	
Aortic bifurcation angle	43.8°	39.8°	.42

TASC, TransAtlantic InterSociety Consensus.

tracking the catheter over a wire related to wire friction and tortuosity, 2 cases of acute angle of aortic bifurcation (11.1%) that resulted in failure of device delivery to the re-entry site, 1 mechanical failure (5.6%), and 1 case of difficulty tracking the catheter through the lesion (5.6%). The mean ABA in the entire failure subgroup was 39.8° (range, 15°-71°). Ten patients in the failure cohort (58.8%) did have an acute ABA. One technical malfunction occurred with the needle device, and the needle would not deploy.

Complications. In three cases, the Outback catheter created an arteriovenous fistula, but no intervention was performed and no adverse sequelae resulted from this complication. No distal embolization occurred as a result of the intervention. This was documented with a completion angiogram at the conclusion of the case, which is standard protocol for these procedures. No bleeding related to Outback LTD needle puncture was identified. One extravascular revascularization occurred; in this case, the subintimal crossing inadvertently entered the subsartorial space by rupturing the adventitia, and successful true lumen re-entry was established with the Outback LTD. This was not recognized at the time of the original procedure. A substantial subsartorial pseudoaneurysm was identified 1 week after the initial procedure and was treated successfully with placement of a Viabahn stent graft (W L Gore and Assoc, Flagstaff, Ariz), thus creating a percutaneous extravascular bypass.[8]

DISCUSSION

Endovascular therapy is regarded as the first-line procedural treatment for patients with symptomatic TASC II A, B, and C femoropopliteal lesions. In addition, these techniques are increasingly applied in the treatment of patients of high surgical risk with TASC II D lesions and CLI. During the last decade, periprocedural failure rates have been diminished with the use of nitinol stent technology,[9] and new developments in the area of debulking and drug elution may improve long-term outcomes. The Outback LTD was developed to overcome procedural failures and improve treatment success after subintimal passage through a CTO.

This series describes the use of the Outback LTD re-entry catheter in the treatment of femoropopliteal CTOs where re-entry could not be established with conventional wire and catheter techniques. Approximately one-fifth of infrainguinal subintimal recanalizations fail because of failure to re-enter the true lumen distal to the CTO.[2,3] In our series, a re-entry device was required in 20.9% of femoropopliteal CTO cases. Technologic advances such as the Outback LTD re-entry device have been designed specifically to overcome this well-known limitation. Previous reports have cited variable success rates with currently available re-entry devices. At our institution using a single device in an isolated vascular territory, we report an overall success rate of 64.5%. The use of a re-entry device can substantially increase the overall technical success rates in the treatment of CTOs.

Only four complications occurred as a result of the Outback LTD catheter, three were arteriovenous fistulas that were not clinically significant and resulted in no adverse sequelae. One resulted in extravascular revascularization of the femoropopliteal lesion and has been reported independently.[8]

Similar to other reports, failure to achieve successful endoluminal therapy was most often due to failure of the device to re-enter the true lumen.[2,4-7] The current review has identified heavy calcification at the proposed re-entry site as the primary reason for device failure. In the series from Hausegger et al,[6] two failures (20%) to re-enter the true lumen were attributed to heavy calcification of the artery. Specifically, the investigators described a heavily calcified occlusion that impaired the free rotation of the Outback catheter. In addition, the needle could not be deployed in one of those cases due to the heavy calcification. Similarly, calcification was described as a major factor in the five failures (21%) reported by Setacci et al.[2]

The degree of calcification at the site of re-entry was judged by the amount of calcium visible on the procedural angiogram. Specifically, we observed whether calcium was lining the vessel on no side, one side or both sides, or filling the lumen. In the failure cohort of our series, moderate or severe calcification at the re-entry site specifically made success less likely. In one case in our series, the heavily calcified occlusion made it impossible to track the catheter through the subintimal plane adjacent to the calcification even after predilation with balloon angioplasty. In other cases with heavy calcification, the catheter could be directed and oriented appropriately; however, the needle could not penetrate the calcium to achieve re-entry. This is not unexpected, because the needle is a 23-gauge nitinol construct and is easily deflected when deployed in a region with significant calcification. This deflection can inadvertently rotate the device thus changing orientation and resulting in unsuccessful true lumen re-entry.

Two failures of subintimal recanalization occurred as a result of an acutely angled aortic bifurcation (37° and 28°). Angiographic review of these cases revealed significant acute aortic bifurcation with calcification extending into the common iliac arteries, which did not allow for splaying

of the aortic bifurcation, notwithstanding the use of a stiff 0.035-inch wire. In these cases, the Outback LTD catheter could not be delivered over the aortic bifurcation despite the use of a larger 7F sheath. This failure to advance over the bifurcation is the result of the stiff nose cone that houses the nitinol re-entry needle. Although not a statistically significant limitation in our review, this technical consideration should be considered before attempted re-entry with the Outback LTD catheter.

Additional failures of the Outback catheter to aid in re-entry occurred as a technical problem with the actual device. In three cases, difficulty tracking the catheter over the wire related to friction was problematic. In these cases, the catheter tracked easily over the wire initially and re-entry was achieved with the aid of the catheter. However, once the wire was advanced into the true lumen at the re-entry point, the catheter became adherent to the wire, and the wire and catheter had to be removed together, thus losing access to the true lumen. The conclusion in these cases was that friction of the wire on the inner hydrophilic catheter coating had resulted in the wire binding to the catheter. One technical malfunction occurred with the needle device and the needle would not deploy.

Although no significant learning curve was identified when the success rates of the various device users within the vascular division were examined, this may be another possible contributing factor to failure of re-entry using the Outback LTD catheter. Four of the 50 cases using the Outback LTD catheter represented the lone application of the device by the attending surgeon. In three of these cases, the surgeon was not successful re-entering the true lumen distal to the occlusion. Only three (42.9%) of the seven surgeons using this device were successful on their initial use. The Outback LTD catheter is not a difficult device to use, but it is intuitive that repeated use would increase comfort level and success rate with the device.

The primary limitations of this study are inherent to those of retrospective design and small sample size. In addition, the series included operators with various levels of experience with the device. The small sample size coupled with large number of operators may have concealed a significant learning curve. Another limitation brought on by the retrospective design was our method of grading the calcification at the re-entry site using procedural angiograms. Plain angiography is inferior to computed tomography angiography as a modality of imaging to grade calcification. In our practice, however, computed tomography angiography is not routinely used before intervention because it adds expense, radiation exposure, and contrast toxicity.

CONCLUSIONS

Although the Outback LTD re-entry catheter can be successful in extending the applicability of endovascular management to difficult femoropopliteal occlusions, when conventional methods of lumen re-entry fail, it is not uniformly successful in current clinical practice. However, the Outback LTD catheter is safe in the femoropopliteal location. Significant calcification at the proposed re-entry site is a strong predictor of device failure.

AUTHOR CONTRIBUTIONS

Conception and design: SS, DB, RC, MM, RR, LM
Analysis and interpretation: SS, LM
Data collection: SS, DB
Writing the article: SS, LM
Critical revision of the article: SS, DB, RC, MM, RR, LM
Final approval of the article: SS, DB, RC, MM, RR, LM
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